UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT LITIGATION	MDL No. 1592 (MLW) This Document Relates to All Actions

JOINT OPPOSITION TO COLUMBIA'S MOTION TO STAY LITIGATION PENDING CONCLUSION OF REEXAMINATION AND REISSUE PROCEEDINGS IN THE PATENT AND TRADEMARK OFFICE SUBMITTED ON BEHALF OF GENENTECH, INC., BIOGEN IDEC MA INC., GENZYME CORPORATION, ABBOTT BIORESEARCH CENTER, INC., AND JOHNSON & JOHNSON

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PRELIMINARY STATEMENT

For twenty-four years Columbia has prosecuted patent applications derived from a single 1980 disclosure, repeatedly prolonging the process through extensions and dismissed appeals. During this prosecution, Columbia had more than ample opportunity to express its views to the PTO. Now, faced with multiple challenges to the '275 patent, Columbia seeks to return to the PTO to conduct reexamination and reissue proceedings. In the meantime, Columbia seeks to stay this litigation, thereby preventing plaintiffs from achieving prompt and final resolution of their claims. Enough is enough. Columbia's Motion to Stay should be denied.

Columbia's request to stay this litigation highlights the lengths to which Columbia will go to stall a judicial resolution of this dispute. Initially, in response to plaintiffs' claims, Columbia did not invoke any of the PTO procedures for reconsidering a patent of questionable validity. Instead, Columbia delayed these cases for months, first by filing motions to transfer, and then by reversing its position and moving to initiate MDL proceedings. Now, just as the MDL litigation Columbia fought for is about to advance in earnest, Columbia seeks to stay all judicial action, based upon a reexamination request filed by a third party and a reissue application Columbia has not yet even filed, until the completion of PTO proceedings – a process that could take years and still fail to resolve the parties' dispute.

Staying this action will substantially prejudice the plaintiffs and harm the public interest. Columbia knows that while it attempts to overcome the deficiencies in its patent through further prosecution before the PTO, uncertainty will hang over the plaintiffs and their products. As a result, a stay will force plaintiffs to decide whether to pursue their current path of drug development, which Columbia seeks to dominate with its invalid and unenforceable patent, to

alter the course of their drug development to avoid Columbia's patent and thereby delay the introduction of new products, or to cave in to Columbia's illegitimate royalty demands because they cannot obtain expeditious relief from the courts.

Columbia also knows, despite its disingenuous statements to the contrary, that a stay here will provide no benefits to counter the gross prejudice it would cause. The ex parte PTO proceedings cannot resolve all of the issues in this litigation, do not provide the plaintiffs any meaningful opportunity to participate, and are unlikely to result in the complete invalidation of Columbia's patent. As a result, if this case is stayed, it is all but certain that plaintiffs will return to this Court to assert many if not all of the claims they are pressing now. Thus, a stay of this action will not promote judicial efficiency.

Given Columbia's substantial resources, penchant for calculated delay, and threatened (but as-yet-unfiled) reissue application, the PTO's repeat consideration of the '275 patent will almost certainly last for years. By contrast, the parties have exchanged schedules that will allow the Court to construe the '275 patent and consider dispositive motions within a year. Thus, the double patenting issue can be resolved more quickly and definitively in this forum than in the PTO. If the result of this proceeding is to invalidate the patent, the PTO proceedings will end.

It would be a severe blow to the plaintiffs and to the public interest if this Court were to permit this invalid patent to remain in force while Columbia undertakes a lengthy reiteration of its ex parte patent prosecution. Accordingly, Columbia's motion for a stay should be denied.

BACKGROUND

The History of the ’275 Patent

The plaintiffs in these cases seek declarations that U.S. Patent No. 6,455,275 (the “’275 patent”) is invalid and unenforceable and that they do not owe royalties under their respective license agreements with Columbia. The plaintiffs contend, among other arguments, that the ’275 patent is invalid for obviousness-type double patenting over earlier Columbia patents, known as the “Axel patents,” which, like the ’275 patent, claim cotransformation. Plaintiffs also claim that the ’275 patent is unenforceable by reason of prosecution laches and inequitable conduct.

The application for the first Axel patent – U.S. Patent No. 4,399,216 (the “ ’216 patent”) – was filed over 24 years ago. Before the expiration of the ’216 patent, Columbia filed several continuation applications that yielded two more patents on the same invention: U.S. Patent No. 4,634,665 (the “ ’665 patent”) and U.S. Patent No. 5,179,017 (the “ ’017 patent”). Notably, because these two patents claimed what was had previously been claimed in the ’216 patent, the Patent and Trademark Office (“PTO”) issued these patents only after Columbia filed a terminal disclaimer, i.e., a disclaimer of any rights in these patents extending beyond the ’216 patent’s expiration date. Thus, Columbia’s 17-year monopoly over the technology first disclosed in the ’216 patent and again in the ’665 and ’017 patents should have ended in August 2000, when this technology passed into the public domain by virtue of the expiration of the ’216, ’665, and ’017 patents.

In 1995, 15 years after it first applied for the ’216 patent, and five years before the expiration of the ’216 patent, Columbia filed yet another continuation application based on the ’216 patent’s disclosure. As with the ’665 and ’017 patents, this new application claimed the

same invention as the first patent or an obvious variant thereof. While prosecuting this application, the PTO rejected Columbia's claims on double patenting grounds. Rather than agreeing to a terminal disclaimer, however, Columbia contested the PTO's double patenting rejections for seven years in the hope that it could extend its lucrative patent monopoly. Finally, in May 2002, a PTO examiner, different from the examiner who initially repeatedly rejected the application, allowed certain pending claims, which issued in September 2002 as the '275 patent. Remarkably, the '275 patent will not expire until 2019, thirty-nine years after the original application was filed.

Before the '275 patent issued, Columbia licensed rights to the '216 patent family to numerous leading biotechnology companies. Over the last decade, Columbia collected hundreds of millions of dollars under these licenses. Nearly two years after the original '216 patent expired, Columbia suddenly informed plaintiffs that they would be obliged to resume paying royalties under their respective licenses for another seventeen years.

The Cases Challenging the Validity of the '275 Patent

On April 11, 2003, plaintiff Genentech filed suit against Columbia in the Northern District of California alleging the invalidity and unenforceability of the '275 patent based on double patenting, prosecution laches, and inequitable conduct. In the following months, six additional cases were filed in a variety of district courts similarly alleging that the '275 patent was invalid for double patenting, among other theories, including a case brought in this Court by Biogen, Genzyme, and Abbott and a case brought by Johnson & Johnson in the Southern District of New York.

Columbia consistently acted to delay the suits. For example, in the Genentech case, Columbia opposed Genentech's attempt to implement a prompt schedule, arguing that Columbia's as yet unfiled motions to transfer other cases to the Northern District of California justified delay. See Joint Initial Case Management Statement, at 6, 8, Genentech, Inc. v. Trs. of Columbia Univ., No. C 03-1603 VRW (N.D. Cal. filed Apr. 15, 2003) (Tab 1).[1] The Court rejected Columbia's proposed schedule in favor of Genentech's more expeditious plan. See Minute Order dated October 7, 2003. See Oct. 7, 2003 Minute Order, Genentech (Tab 2).

When Genentech attempted to proceed with discovery, Columbia refused to provide meaningful responses to discovery requests and documents until a protective order was entered. See, e.g., Columbia's Response to Genentech's First Set of Interrogatories at 5, Genentech (Tab 3). But Columbia dragged its feet and ultimately did not agree to a protective order despite lengthy negotiations.

On November 7, 2003, Genentech noticed the depositions of the inventors and prosecutor of the '275 patent. Columbia refused to make these witnesses available. See Letter from David Gindler, Irell & Manella LLP, to the Honorable Vaughn R. Walker, Northern District of California (November 19, 2003) (Tab 4). In response to Genentech's attempt to compel the witnesses to appear, Columbia responded by asserting, for the very first time, that it intended to seek multidistrict consolidation. See id. Columbia embraced this tactic despite having previously expressly argued that MDL was not an appropriate procedure for the '275 patent

[1] Citations to all record sources are to Appendix in Support of the Joint Opposition to Columbia's Motion to Stay Litigation Pending Conclusion of Reexamination and Reissue Proceedings in the Patent and Trademark Office, filed herewith. Citations to materials appearing in that Appendix are to the Declaration of Claire Laporte contained therein or to materials appearing behind a tab. In the latter case, the material will be cited by title and tab number.

disputes. See, e.g., Mem. Supp. Mot. to Transfer at 13, Immunex Corp. et al. v. Trs. of Columbia Univ., No. CV 03-4349 MRP (CWx) (C.D. Cal. filed June 18, 2003) (Tab 5) ("the convenience of the parties and witnesses and the interests of justice would not be served by MDL treatment."); Def.'s Mem. Supp. Mot. to Transfer Pursuant to 28 U.S.C. § 1404(a), at 13, Biogen, Inc. et al. v. Trs. of Columbia Univ., No. CV 03-11329 MLW (D. Mass. July 15, 2003) (Court's Docket No. 17) ("Despite the common questions of law and fact in the four lawsuits against Columbia, Multidistrict Litigation ("MDL") would not address Columbia's concerns."). Only by resorting to this tactic, which it had previously disavowed, was Columbia able to stay discovery in the Genentech suit and thwart discovery in all the suits. See Dec. 2, 2003 Order, Genentech (Tab 6).

Columbia stonewalled plaintiffs in other areas as well. Nearly three months ago, on March 22, 2004, plaintiffs wrote to Columbia asking for Columbia's consent to review the prior deposition testimony of several key witnesses, including named inventors of the Axel patents, in the related cases Biogen, Inc. v. Berlex Laboratories, Inc. and Trustees of Columbia University v. Roche Diagnostics, Inc., which could not be released without Columbia's consent pursuant to the respective protective orders in those cases. See Letter from Claire Laporte, Foley Hoag LLP, to David Gindler, Irell & Manella LLP (March 22, 2004) (Tab 7). Columbia did not respond. On April 15, 2004, after the multidistrict transfer motion had been resolved, plaintiffs again requested consent to review the prior deposition testimony. See Letter from Claire Laporte, Foley Hoag LLP, to David Gindler, Irell & Manella LLP (Apr. 15, 2004) (Tab 8). Columbia again failed to respond.

The Request for Reexamination and Columbia's Motion to Stay

At no time during this period did Columbia seek reexamination or reissue of the '275 patent. While Columbia's motion for multidistrict litigation was pending, however, a third party, the Public Patent Foundation, filed a Request for Ex Parte Reexamination of the '275 patent on February 25, 2004. None of plaintiffs had any knowledge of the decision to file this Request, and Columbia states that it similarly did not have any knowledge of the Request. Continuing its pattern of delay, Columbia took no action whatsoever upon learning of the reexamination request. Columbia still did not file a reissue application, although by that time it must have been well aware that its patent was "wholly or partly inoperative or invalid," as it must be to satisfy the requirements of the reissue statute. See 35 U.S.C. § 251. Nor did Columbia seek to stay proceedings in any court or before the Judicial Panel on Multidistrict Litigation.

In March, 2004, Columbia sent letters to most of the plaintiffs asserting breach of the license agreements and stating that the license agreements would terminate unless the plaintiffs "cured" by paying the royalties allegedly due on the '275 patent. On April 7, 2004, Biogen and Genzyme filed a motion for preliminary injunction, seeking to enjoin the termination of their licenses. In their brief, they submitted a detailed demonstration that the '275 patent is invalid for double-patenting and unenforceable by reason of prosecution laches. In responding to the motion, Columbia said not one word in defense of its patent, tacitly conceding its invalidity and unenforceability, yet it took no action to repair the defects of its patent at the PTO.

When the PTO granted the Public Patent Foundation's Request for Reexamination on May 6, 2004, Columbia still took no action. Instead, it waited until the eve of this Court's hearing on Biogen and Genzyme's preliminary injunction motion – three months after the

reexamination was filed and over a month after it was granted – before moving for a stay. Indeed, Columbia delayed disclosing that it would seek a stay until this Court ordered Columbia to meet and confer with the plaintiffs on the implications of the pending reexamination.

The Motion for Stay is based on the reexamination proceeding and a hypothetical reissue application Columbia claims that it intends to file. Columbia could have filed a reissue application under 35 U.S.C. § 251 at any time after the '275 patent issued in September 2002, but did not do so and as of this date still has not done so. Before filing its Motion for Stay, Columbia never indicated that it might seek reissue. Despite their request, Columbia has refused to provide plaintiffs with any information concerning the scope of its intended reissue application.

In a letter to the Court dated June 10, 2004, weeks after the Court scheduled the status conference, Columbia once again sought to delay the litigation. This time, it sought to postpone both the hearing on the Motion for Preliminary Injunction brought by Biogen and Genzyme and the MDL status conference, insisting that its eleventh-hour request for a stay should be heard first.

ARGUMENT

I. THE COURT SHOULD EXERCISE ITS DISCRETION AND DENY COLUMBIA'S MOTION TO STAY.

The Court need not and should not stay this litigation pending reexamination or reissue. The Federal Circuit has acknowledged that litigation and PTO procedures are distinct. See, e.g., Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427 (Fed. Cir. 1988) ("[L]itigation and reexamination are distinct proceedings, with distinct parties, purposes, procedures, and outcomes."). Consequently, litigation and reexamination or reissue may run concurrently. Id. at 1428. This is

because the proceedings have different standards of proof, and a court may consider many challenges to patent validity and enforceability that the PTO cannot. Id. at 1427 ("duplication of effort does not occur because the PTO and the courts employ different standards of proof when considering validity, and the courts, unlike the PTO during a reexamination of patent claims, are not limited to review of prior art patents or printed publications").

There is a significant benefit that may result from concurrent proceedings in the PTO and in this Court. If the litigation results in a judgment of invalidity or unenforceability of the '275 patent while the PTO proceedings are pending, those proceedings will simply terminate. See MPEP § 2286 (upon issuance of final judicial holding of invalidity or unenforceability, the claims held invalid or unenforceable "will be withdrawn from consideration in the reexamination").

The decision whether to grant a stay of litigation pending reexamination or reissue is within the sound discretion of the district court. See, e.g., Wayne Automation Corp. v. R.A. Pearson Co., 782 F. Supp. 516, 517 (E.D. Wash. 1991); Toro Co. v. L.R. Nelson Corp., 1984 WL 1244, at *2 (C.D. Ill. July 25, 1984). To determine whether to stay litigation pending reexamination, "[t]he court must weigh the competing interests presented by a particular set of facts." Gladish v. Tyco Toys, Inc., 29 U.S.P.Q.2d 1718, Civ. No. 5-92-1666 WBS/JFM, 1993 WL 625509, at *1 (E.D. Cal. Sept. 15, 1993). Specifically,

> [a]mong the considerations to be balanced are hardships to the parties resulting from the granting or denial of the stay as well as "the orderly course of justice measured in terms of simplifying or complicating of issues, proof, and questions of law which could be expected to result from a stay."

Id.; Starlight Assoc. v. Berkey-Colortran, Inc., 201 U.S.P.Q. 307, 307 (D. Del. 1978).

A. Columbia's Alleged Preference for a Determination of Validity by the PTO is Belied By Columbia's Failure to Seek Reexamination or Reissue.

Columbia's asserted preference for review of the '275 patent by the PTO is contradicted by Columbia's failure to seek reexamination or reissue. Columbia first learned of the plaintiffs' allegations of invalidity and unenforceability on April 11, 2003 when Genentech filed its first action challenging the '275 patent. Numerous other cases were also filed making similar allegations. If Columbia truly had been interested in having the validity of the '275 patent decided by the PTO, Columbia could have sought reexamination or reissue at any time since the patent issued in September 2002 and at the latest by April 2003 when Genentech brought suit. See Starlight, 201 U.S.P.Q. at 307 (denying stay pending reissue because "[t]he reissue application procedure, available since March 1, 1977, was not utilized until June of 1978, when an application was finally filed"). Instead, Columbia took no action in the PTO, and now seeks a stay of this litigation based on the mere happenstance that a third party, Public Patent Foundation, requested reexamination in 2004. As of today, Columbia itself has neither requested reexamination nor applied for reissue.

While Columbia asserts in its motion that it intends to invoke the PTO reissue procedure "in the immediate future" (Mot. to Stay at 1, 4), Columbia has not explained why it waited so long to submit a reissue application despite its evident recognition of the patent's infirmities. Were Columbia serious about seeking reissue it could and should have done so before moving for a stay. Moreover, Columbia has also failed to disclose the basis upon which it intends to seek

reissue or the scope of its application.[2] Columbia's reissue application will have to demonstrate that "through error without deceptive intention" the '275 patent is "wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent . . . ." 35 U.S.C. § 251. Without more information regarding Columbia's reissue application it is impossible for the Court or the parties to make any determination concerning the potential scope of the reissue proceedings.

Indeed, Columbia's assertion that it intends to seek reissue is an admission that the '275 patent is in fact inoperative or invalid. See 35 U.S.C. § 251. That admission, coupled with Columbia's failure to contest the showing of invalidity in Biogen's and Genzyme's preliminary injunction papers, is revealing. Where even the patentee concedes that some, if not all, of the claims of the patent-in-suit are invalid, a prompt judicial determination of invalidity to avoid the prejudice of lingering uncertainty is especially appropriate. As discussed below, invalidity can be determined more quickly in this litigation than in the PTO. See section II.B. Accordingly, rather than a stay, a schedule that allows for expeditious resolution of these cases is most appropriate.

B. Columbia's Motion To Stay Should Be Denied Because It Is Brought For Dilatory Purposes.

Where it is determined that a party has sought to use reexamination for the purpose of intentional delay, courts generally deny requests for stay. See Toro Co., 1984 WL 1244, at *2

[2] Because of the difficulty plaintiffs face in making arguments concerning a reissue application which has not yet been filed, plaintiffs requested that Columbia reveal the basis of the threatened reissue application and the nature of the corrections that Columbia seeks to the issued patent. See Letter from Claire Laporte, Foley Hoag LLP, to David Gindler, Irell & Manella LLP (June 10, 2004) (Tab 9). Columbia refused to provide this information, leaving plaintiffs to argue in the dark. See Letter from David Gindler, Irell & Manella LLP, to Claire Laporte, Foley Hoag LLP (June 11, 2004) (Tab 10).

(noting that the reexam and stay could have been sought much earlier in the litigation and acknowledging that the defendant "seriously questions plaintiff's good faith in interposing the motion for stay, in view of the timing of the same in the procedural sequence of this litigation"); see also Freeman v. Minn. Mining & Mfg. Co., 661 F. Supp. 886, 888 (D. Del. 1987) ("To allow 3M to now use the reexamination process to get this case stayed would be to allow a defendant to use the reexamination as a mere dilatory tactic.").

Here, Columbia's Motion is part of a long campaign of dilatory tactics aimed at delaying a decision concerning the validity of the '275 patent while maintaining a cloud of uncertainty over the biotechnology industry. The Court should not allow Columbia, at this stage in the proceedings, to again delay this litigation through procedural detours. See Enprotech Corp. v. Autotech Corp., 15 U.S.P.Q.2d 1319, No. 88C4853, 1990 WL 37217, at *2 (N.D. Ill. 1990) ("We are too far along the road to justify halting the journey while the defendant explores an alternate route.").

1. Columbia's delay is part of its continuing effort to unlawfully exploit its cotransformation technology.

Columbia's Motion is part of a strategy of purposeful delay that began during prosecution of the '275 patent. Columbia's prolonged prosecution allowed it to double the length of time it could profit from the contransformation technology. The application that matured into the '275 patent was filed 15 years after the original application to which it claims priority. Due to Columbia's dilatory prosecution, it took another seven years for the '275 patent to issue. By the time the '275 patent issued, Columbia's three earlier patents covering the same invention had already expired – 22 years after it filed the first application covering cotransformation.

Columbia's Motion to Stay is yet another improper attempt to extend the period of enforceability of the '275 patent, because if this litigation were to proceed, the patent would be invalidated. See Wayne Automation Corp., 782 F. Supp. at 518 (denying stay where patentee had repeatedly delayed prosecution of the patent and the non-movant had argued that the "Motion for Stay is the latest in a long series of delaying tactics involving the patent at issue here."). Thus, by delaying this litigation, Columbia seeks to prolong the length of time it can collect royalties.

2. This litigation has already been delayed as a result of Columbia's dilatory tactics.

Columbia argues that a stay is warranted because the consolidated cases "are in their earliest stages." (Mot. to Stay at 14.) That argument ignores the fact that some of the consolidated cases have been pending for more than a year. To the extent that progress has been slow, the fault lies with Columbia. Columbia's argument that no scheduling order has been entered and no trial date has been set overlooks the fact that the actions were proceeding apace until Columbia belatedly initiated MDL proceedings. Columbia's motion for MDL delayed the consolidated cases by more than four months.

The impact of Columbia's delay tactics is particularly stark in the Genentech action. From the inception of its litigation against Columbia, Genentech pressed for an expedited claim construction schedule and actively pursued discovery. In response, the court entered a schedule which provided for a claim construction hearing on March 29, 2004 – a date now long since past. See Joint Pre-Claim Construction Schedule, Genentech (Tab 11). Despite this schedule, Columbia delayed discovery and other procedural matters until December 17, 2003 when the court stayed all pretrial proceedings pending resolution of Columbia's MDL motion. Columbia

was therefore responsible for derailing discovery and claim construction. Indeed, dispositive motions might have been filed by now but for Columbia's delays. Certainly, all of the consolidated cases would be significantly advanced were it not for Columbia's dilatory tactics.

C. Plaintiffs Will Be Prejudiced By Any Further Delay In The Litigation Of Their Claims Against Columbia.

A stay is also inappropriate here because it would result in significant prejudice to plaintiffs. A stay should not be granted when it will cause prejudice or present a clear tactical disadvantage to the non-moving party. See Xerox Corp. v. 3Com Corp., 69 F. Supp. 2d 404, 407 (W.D.N.Y. 1999). Although Columbia contends that "a stay of these actions poses no threat of prejudice to plaintiffs," Motion at 2, where, as here, the stay is a dilatory tactic by the moving party, courts have recognized that such a stay would result in prejudice. See, e.g., Xerox Corp., 69 F. Supp. 2d at 407 (holding that a request for stay that had "at least some dilatory tactical motive behind it" would result in prejudice to the non-movant). Columbia's motion makes no mention of any hardship Columbia would suffer if a stay were denied. Furthermore, swift resolution of this dispute is necessary to erase the uncertainty surrounding the '275 patent.

1. A stay will increase the uncertainty that currently threatens plaintiffs' business and the public interest.

Further postponing final resolution of Columbia's bid to extend its patent monopoly will greatly prejudice plaintiffs and the public without promoting any countervailing interests. The plaintiffs in this litigation, several of the world's leading biotechnology companies, all manufacture life-saving drugs using cotransformation technology that Columbia may assert is encompassed by continuing patent rights. Until a court finally resolves the validity of the '275 patent, Columbia will be able to threaten the biotechnology industry with the specter of a lawsuit

seeking hundreds of millions of dollars in contract or patent infringement damages – even while it refuses to explain on what possible grounds its patent could survive plaintiffs' legal challenges. A stay of this case pending reexamination will extend the cloud of uncertainty currently hanging over plaintiffs' products.

Courts recognize that uncertainty of this kind magnifies the prejudice to a plaintiff should a case be stayed. See Gladish, 1993 WL 625509, at *3 (denying a stay where a non-moving party "has a strong interest in concluding this lawsuit without delay," noting that "customers apparently are informed that plaintiff claims infringement"); Enprotech Corp., 1990 WL 37217, at *1 (denying a stay where "[p]laintiff's customers apparently are advised that defendant contends that plaintiff is infringing; plaintiff wants to have the matter resolved").

Columbia seeks to stay this litigation at a time when the plaintiffs' rights are most in limbo. Columbia has purported to terminate all but one of the plaintiffs' license agreements. (Mot. to Stay at 3.) Such termination would potentially render the plaintiffs liable for patent infringement. Cordis Corp. v. Medtronic, Inc., 835 F.2d 859, 864 (Fed. Cir. 1987) (finding that termination of the license agreement would irreparably injure licensee because it would lead to lost market share and possible litigation against licensee and its customers). Indeed, Columbia threatens to bring infringement counterclaims should the litigation not be stayed. (Mot. to Stay at 2.) Thus, until this case is ultimately resolved in the courts – a period that Columbia would have last years longer than necessary – the plaintiffs face the uncertainty of potential infringement liability.

Columbia asserts that "[a] stay will not increase plaintiffs' financial exposure in these lawsuits" because plaintiffs will not owe any royalties during the pendency of the litigation if the patent is invalidated. Id. at 15-16. Upon hearing this argument, Biogen and Genzyme requested that Columbia unequivocally disclaim all right to any royalties that might accumulate during the period before the patent is invalidated. Columbia waffled. See Letter from Claire Laporte, Foley Hoag LLP, to David Gindler, Irell & Manella LLP (June 11, 2004) (Tab 12); Letter from David Gindler, Irell & Manella LLP, to Claire Laporte, Foley Hoag LLP (June 11, 2004) (Tab 13). Nor has Columbia disavowed the right to collect infringement damages for the period during which the stay is in force.

The uncertainty that Columbia has created – and seeks to perpetuate – also threatens the public interest. Plaintiffs manufactured drugs of immeasurable public benefit under their licenses to the Axel patents. As long as the question of the validity of the '275 patent remains unresolved, however, if they undertake to develop new manufacturing techniques to avoid any potential claims of infringement, the launch of beneficial new products may be delayed, to the detriment of patients. Alternatively, if companies acquiesce in Columbia's royalty demands in order to eliminate the continuing business uncertainty, consumers may be forced to pay higher prices for drugs as a result of royalty costs being passed on to them. Either way, the public will suffer.

Plaintiffs' well-established right to eliminate uncertainty via a declaratory judgment action should not be undermined simply because the PTO is conducting a more limited review of the patent-in-suit. See Arrowhead Industrial Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 735

(Fed. Cir. 1988) (noting that the intent of the Declaratory Judgment Act was to resolve uncertainty suffered by potential infringers); see also Am. Ceramicraft, Inc. v. Eisenbraun, Civ. No. 92-285, 1993 WL 498863 at *10 (D.N.J. June 16, 1993) (noting that "[a]s long as the validity of the '325 patent remains in doubt, none of the parties here can put this matter behind them and go about the business of manufacturing and selling"). The cases on stays pending reexamination reflect the fact that the courts have been reluctant to derail declaratory judgment actions.

Indeed, with only one exception, the cases cited by Columbia do not involve the grant of a stay over the objections of a declaratory judgment plaintiff.[3] Courts generally deny stays in such circumstances. See Arctic Cat, Inc. v. Injection Research Specialists, Inc., No. Civ. 01-543 MJDRLE, 2003 WL 22047872 (D. Minn. Aug. 29, 2003) (denying motion by declaratory judgment defendant to stay discovery related to patent in reissue proceedings); Am. Ceramicraft, 1993 WL 498863, at *10 (denying defendant's motion to stay plaintiff's declaratory judgment action pending reexamination initiated by defendant); Enprotech Corp., 1990 WL 37217, at *3 (same); Yates-American Machine Co. v. Newman Machine Co., 694 F. Supp. 155, 159 (M.D.N.C. 1988) (denying defendant's motion to stay declaratory judgment action pending reissue).

[3] In the one exception, Thomas & Betts Corp. v. Tishman Research Corp., No. 86 Civ. 1926, 1986 WL 13455 (S.D.N.Y. Nov. 17, 1986), the Court granted defendants' motion to stay a declaratory judgment action pending reexamination because, in contrast to this case, both parties in Thomas & Betts filed reexamination applications, and the plaintiff itself acknowledged that trial should be delayed until the conclusion of reexamination.

2. The plaintiffs have already invested time, effort, and expense in litigating the issue of MDL transfer.

Allowing Columbia to impose further delay, after the parties and the federal judiciary have invested considerable time and resources in the MDL process – which Columbia initiated – would greatly prejudice plaintiffs. See In re Laughlin Prods., Inc., 265 F. Supp. 2d 525, 534 n.8 (E.D. Penn. 2003) (granting only partial stay, emphasizing that "though this case is still in its early pretrial stages, the parties have expended some amount of resources in litigating transfer issues before the MDL Panel. Moreover, the federal judicial system has invested considerable time in bringing this MDL to its present status . . . ."); Xerox Corp., 69 F. Supp. 2d at 407. Because Columbia chose to pursue MDL, Columbia should not now be allowed to abandon that course for its own tactical advantage. See Enprotech Corp., 15 U.S.P.Q.2d at 1320 ("We are too far along the road to justify halting the journey while the defendant explores an alternate route.").

II. THE PTO WILL NOT PROVIDE A BETTER FORUM FOR DETERMINATION OF THE VALIDITY OF THE '275 PATENT.

Columbia also argues that the Court should stay the litigation to allow the PTO to address the issue of the validity of the '275 patent first. There is no legal basis for the alleged superiority of a ruling from the PTO. To the contrary, the Supreme Court commented in Lear, Inc. v. Adkins, 395 U.S. 653 (1969), that:

> [a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving invalidity.

Id. at 670.

Columbia argues that the PTO's expertise in evaluating patent validity makes the PTO the best forum for the resolution of plaintiffs' double patenting challenge. The PTO has already spent years examining the '275 patent. That very process led to the issuance of a patent that has been recognized by many as being invalid for double patenting. As a result, leading companies in the industry have brought suit for a judicial determination of invalidity.

Courts have held that any benefit that may be gained by waiting for the PTO's expertise can be outweighed by prejudice to the plaintiff caused by significant delay. See Xerox Corp., 69 F. Supp. 2d at 408; Starlight Assoc., 201 U.S.P.Q. at 307 ("Any benefit to be obtained by waiting for the decision of the Patent Office [on a reissue application] . . . is outweighed by the additional delay involved.").

Importantly, in this case unlike the typical reexamination, the common issues presented by plaintiffs are largely dependent on legal doctrines that require the legal expertise of this Court. See In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993) ("Obviousness-type double patenting is a question of law.") (citing Tex. Instruments Inc. v. Int'l Trade Comm'n, 988 F.2d 1165, 1179 (Fed. Cir. 1993)). In fact, in granting the '275 patent, the Patent Office explicitly indicated that it was uncertain as to the state of the law of obviousness-type double patenting. In response to Columbia's arguments that the examiner's double patenting rejections failed to articulate a motivation to combine necessary under "settled law," Amendment at 6-7, Application Serial No. 08/484136, File History (Jan. 30, 2002) (Tab 14), the examiner indicated his uncertainty as to the state of the law on obviousness-type double patenting. Office Action at 3, Application Serial No. 08/484,136, File History (May 6, 2002) (Tab 15) ("[F]ollowed by a reconsideration of the

unsettled state of the case law on this point ... a withdrawal of the obviousness-type double patenting rejection for those claims is appropriate.").

The current situation contrasts with the vast majority of reexamination proceedings. In a typical reexamination, the PTO applies its technical expertise to evaluate a prior art reference that was not raised during the original prosecution and determines whether the new reference renders the claimed invention anticipated or obvious. In that situation, the PTO's technical expertise in evaluating references may be valuable. Unlike this typical situation, where the court may benefit from the PTO's technical expertise, precisely the opposite is true in the instant case. The examiner's statements during prosecution of the '275 patent reveal that it was the PTO which needed guidance from the courts as to the proper application of the legal doctrine of double patenting.

Finally, it is worth noting that, after considering the multiple lawsuits regarding the '275 patent, and after extensive briefing and oral argument, the JPML selected this Court as the proper forum for the litigation of these cases. In their MDL briefing, a number of the parties argued that this Court's familiarity with the Axel patents from presiding over Biogen, Inc. v. Berlex Laboratories, Inc., 113 F.Supp.2d 77 (D. Mass. 2000), aff'd in part, vacated in part, 318 F.3d 1132 (Fed. Cir. 2003), favored transfer of the consolidated litigation to this Court. See Consolidated Br. Opp'n Columbia University's Mot. to Transfer at 12, In re Columbia Univ. Patent Litig., MDL No. 1592 (J.P.M.L. filed Nov. 25, 2003) (Tab 16). This Court therefore has considerable experience, and a mandate from the JPML, that it is the preferred forum for the determination of the validity of the '275 patent.

A. PTO Proceedings Are Not a Suitable Alternative to This Litigation.

As Columbia admits, reexamination and reissue are patent prosecution redux. Indeed, Columbia observes that "reexamination is 'conducted according to the procedures established for initial examination.'" The same is true for reissue proceedings. 37 CFR 1.176; MPEP § 1440. Nevertheless, Columbia maintains that plaintiffs should wait while Columbia goes through the motions with the PTO yet again. This result would benefit no one but Columbia, which seeks to delay the final termination of its patent monopoly by any available means and to use uncertainty and delay to extract as many coerced settlements as possible before it faces the inevitable invalidation of its patent.

Moreover, reexamination and reissue proceedings (if a reissue proceeding is ever initiated) will not provide the plaintiffs with a suitable alternative to litigating their claims against Columbia in this Court. First, the plaintiffs will be provided only a negligible opportunity to participate in the PTO proceedings. Second, a majority of the plaintiffs' claims will not be addressed or considered by the PTO. Third, the statistics cited by Columbia itself indicate that it is more than likely that the PTO proceedings will not wholly resolve this litigation, thereby requiring litigation to proceed in this Court anyway. Lastly, according to the schedules proposed by the parties, this litigation will likely be resolved more quickly than the PTO proceedings.

1. The plaintiffs will have no opportunity to substantively participate in reexamination and reissue proceedings.

Granting Columbia's Motion to Stay would deprive the plaintiffs of the opportunity to participate in the determination of the validity of the '275 patent in a timely manner. Despite

Columbia's disingenuous assertion to the contrary, reexamination proceedings are conducted ex parte. Compare Columbia's Motion to Stay at 5 ("Unlike the typical patent prosecution proceeding, which is conducted on an ex parte basis without public involvement, a reexamination proceeding is open to the public.") with MPEP § 2200 (referring to such proceedings as "Ex Parte Reexamination of Patents"). This means that parties other than the patent examiner or the patentee cannot meaningfully participate in the conduct of the reexamination. See Enprotech Corp., 1990 WL 37217, at *1 (acknowledging that reexamination would provide the third party "little opportunity to participate"); In re AMP, Inc., 212 U.S.P.Q. 826, 826 (Comm'r of Patents & Trademarks, 1981) ("the statutory scheme of reexamination and the implementing rules which provide for an essentially ex parte proceeding with no participation by persons other than the patent owner and the reexamination requester"). Columbia's assertion that "plaintiffs can make their own submission to the PTO explaining the reasons that they contend that the '275 patent is invalid on prior art grounds," is particularly misleading. Mot. to Stay at 6. The regulations cited by Columbia concern the very limited rights of the reexamination requester – i.e., Public Patent Foundation – and would only permit plaintiffs to comment by filing their own new request for reexamination. 37 C.F.R. §§1.550(g), 1.535, thus injecting further delay into the process.

Columbia similarly misrepresents the procedure for reissue. While Columbia states that "PTO procedure allows plaintiffs to submit arguments and evidence to the PTO explaining their contentions that Columbia is not entitled to the '275 patent" (Mot. to Stay at 7), in fact, reissue proceedings provide only the most limited opportunity for participation by third parties. See Unidisco, Inc. v. Schattner, 210 U.S.P.Q. 622, 629 (D. Md. 1981) (denying motion to stay

pending reissue proceedings and noting "the court finds that plaintiff's concern about lack of participation in reissue proceedings is justified."). A third party may only participate in reissue proceedings as a protester under 37 C.F.R. § 1.291, which allows for the submission of just one paper with no further argument or colloquy. See Baker Hughes Inc. v. Kirk, 921 F. Supp. 801, 804 n.3 (D.D.C. 1995) ("[P]rotestors have limited rights. For example, once a protestor submits his protest, he will receive no communications from the PTO . . . the limited involvement of a protestor 'ends with the filing of the protest, and no further submission on behalf of the protestor will be considered . . . .'") (quoting 37 C.F.R. § 1.291(c)); see also MPEP § 1901.07 ("a protestor is not permitted to participate in interviews, appeal a decision by the examiner adverse to the protestor . . . or participate in an appeal by applicant."). By contrast, Columbia can make its position known in numerous ways. For example, it can file new claims, amend claims, respond to office actions, participate in telephone interviews and in-person meetings, and appeal. Moreover, Columbia may take the position that it can file Requests for Continued Examination. A reissue proceeding is therefore nothing more than another ex parte patent prosecution, amounting, in essence, to yet another continuation application.

Indeed, at least one court has acknowledged the limitations on the rights of third parties in reissue proceedings and has noted that declaratory judgment is a more appropriate procedural vehicle to obtain review of an invalid patent. See Hitachi Metals, Ltd. v. Quigg, 776 F. Supp. 3, 12 (D.D.C. 1991) (noting that while Congress intended "to preclude . . . third-party protestors from seeking judicial review of PTO decisions to grant original and reissue patents" it explicitly

authorized third parties "to challenge the validity and enforceability of the patent . . . by initiating a declaratory judgment action.").

Columbia states that because reexamination and reissue proceedings are "open to the public" the plaintiffs will have the opportunity to "monitor" all events. Mot. to Stay at 5-7. Clearly, the opportunity to "monitor" what Columbia does during an ex parte PTO proceeding is no substitute for plaintiffs' litigation of their claims in this Court.

2. The plaintiffs' claims likely will have to be determined by the Court even after reexamination.

Even after PTO review is completed, the great likelihood is that the parties will be forced to begin this litigation anew. As Columbia itself concedes, the PTO only invalidates 10% of the patents it reexamines. See Mot. to Stay at 8 (quoting TAP Pharm. Prods., Inc. v. Atrix Labs., Inc., No. 03-C07822, 2004 WL 422697 (N.D. Ill. March 3, 2004). Thus, 90% of the time the validity and enforceability of the patent are not resolved during reexamination. Moreover, duplication of effort cannot be avoided, because the PTO's findings on validity and claim construction are not binding on this Court. See Whistler Corp. v. Dynascan Corp., No. 88 C 8368, 1993 U.S. Dist. LEXIS 3850, at *19 (N.D. Ill. Mar. 25, 1993).

Columbia also argues that "the PTO will have an opportunity to consider and opine on virtually every major issue in this multidistrict litigation concerning the validity and enforceability of the '275 patent." Mot. to Stay at 14. This argument lacks merit. In fact, the scope of the PTO proceedings is much more limited than this litigation. On reexamination the PTO only considers challenges to patent validity based on prior art patents and printed publications. See MPEP §2214, at 2200-17; 37 CFR §1.150; Ethicon, Inc. v. Quigg, 849 F.2d

1422, 1427 (Fed. Cir. 1988) (noting that "the courts, unlike the PTO during a reexamination of patent claims, are not limited to review of prior art patents or printed publications, but may also consider challenges to validity on other grounds").

The PTO will not consider plaintiffs' allegations of inequitable conduct in either a reexamination or a reissue proceeding. See 37 C.F.R. § 1.291(b) ("Protests raising fraud or other inequitable conduct issues will be entered in the application file, generally without comment on those issues."); MPEP §1901.06; ("The examiner will not, under any circumstances, treat or discuss those arguments or points directed by 'fraud,' 'inequitable conduct,' or 'violation of duty of disclosure.'"); Enprotech Corp., 1990 WL 37217, at *1 ("The reexamination will . . . not, however, determine the inequitable conduct claim pending here."); see also Starlight, 201 U.S.P.Q. at 307.[4] The PTO itself agrees that "[a] court, with subpoena power, is presently the best forum to consider duty of disclosure issues under the present evidentiary standard for finding an `intent to mislead.' The court proceeding involves two actively participating adverse parties. This is not the case in the Office, since even 'protesting' parties are not permitted to participate under the Rules." PTO Notice Regarding Implementation of 37 C.F.R. § 1.56 , 1095 O.G. 16 (Oct. 11, 1988) (Tab 17).

The fact that issues will still have to be litigated in this Court refutes Columbia's contention that a stay pending reexamination will serve to simplify the issues. Mot. to Stay at 9; see Gladish, 1993 WL 625509, at *2 (holding that because two issues would remain, "issuance of

[4] In the context of reissue proceedings, the PTO "no longer investigates and rejects reissue applications under 37 CFR 1.56." MPEP §1448, at 1400-48. Furthermore, "[a]pplicant's statement in the reissue oath or declaration of lack of deceptive intent will be accepted as dispositive except in special circumstances such as an admission or judicial determination of fraud, inequitable conduct, or violation of the duty of disclosure." Id. (emphasis added).

a stay pending reexamination would not serve Congress' intent of simplifying the issues and reducing the complexity of the trial. After the reexamination, the parties would be right back in this court") (internal citations omitted). To the contrary, because the Court will likely make the final decision on this issue of patent validity, a stay of litigation in this case will cause nothing more than further, unnecessary delay. See E.I. DuPont deNemours & Co. v. Phillips Petroleum Co., 711 F. Supp. 1205, 1208 n.9 (D. Del. 1989) ("Where such a stay could result in a tactical advantage to one party or the other, this Court will not employ its discretion to stay the ordinary course of its proceedings simply because the outcome of the Patent Office proceedings may moot the issues remanded,"); Starlight, 201 U.S.P.Q. at 307 (denying motion to stay pending reissue because "[a]ny benefit to be obtained by waiting the decision of the Patent Office, whose decision would be relevant to only some of the issues in this case, is outweighed by the additional delay involved.").

B. The Parties Have Proposed Schedules That Will Be More Expeditious Than Reexamination.

Claim construction and dispositive motions could readily be completed in this litigation before there is any final decision on reexamination by the PTO, thus negating Columbia's argument that the Court may have to conduct claim construction and invalidity analysis twice, once with the current claims and again after reissue and reexamination. Pursuant to this Court's Order, the parties have conferred regarding the schedule for this litigation. The dates proposed

by the parties provide for the submission of claim construction briefs less than one year from now.[5]

The "average pendency of re-examination before the PTO is 19.2 months, not including any appeals." See Xerox Corp., 69 F. Supp. 2d at 406 n.1. An adverse decision by the PTO may then be appealed to the Board of Appeals and the federal courts. 35 U.S.C. § 306; Emhart Indus. Inc. v. Sankyo Seiki Mfg. Co., 3 U.S.P.Q.2d 1889, 1892 (N.D. Ill. 1987). Given the huge benefits Columbia reaps from maintaining the patent and delay, it is likely that Columbia will appeal the final rejection of any claims even if others survive reexamination. Accordingly, under the proposed schedules, these consolidated cases can be litigated to final judgment far more quickly than the reexamination proceedings before the PTO can be concluded.

CONCLUSION

For all of the foregoing reasons, Columbia's Motion to Stay should be denied.

[5] In the Joint Proposed Scheduling Order, Columbia suggests that opening claim construction briefs be filed on January 18, 2005, and the plaintiffs propose that they be filed on March 22, 2005.

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Respectfully submitted,

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